DOM08 – Practices for Quality Preventive Action

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1. Background

1.1. Quality preventive action is a proactive process to identify opportunities for improvement rather than a reaction to the identification of problems/complaints. All members are encouraged to identify needed improvements and potential sources of non-conformities, either technical or concerning the management system.

1.2. To establish the practices for quality preventive action to conform to the requirements of the Department of Forensic Sciences (DFS) Forensic Science Laboratory (FSL) *Quality Assurance Manual*, Division Quality Assurance Manuals, accreditation standards under ISO/IEC 17025:2005, and supplemental standards. These practices bring about continuous improvement through pro-active measures, provide guidelines to identify potential nonconformities, and reduce the likelihood of nonconformities occurring.

2. Definitions

2.1. For purposes of this document, the following terms shall have the designated meanings:

CSS: Crime Scene Sciences

DFS: Department of Forensic Sciences

DOM: Departmental Operations Manual

FSL: Forensic Science Laboratory

PHL: Public Health Laboratory

Q-PAR: Quality Preventive Action Request

3. Scope

3.1. These practices are applicable to quality preventive actions identified by all DFS personnel.

4. Responsibilities

4.1. The Division Director, Deputy Director of Quality, Directorate member and/or Laboratory Manager will:

4.1.1. Receive and initiate/designate initiation of a Quality Preventive Action Request

4.1.2. Ensure that an individual is assigned the responsibility of handling the quality preventive action.

4.1.3. Ensure that the quality preventive action plan is implemented.

4.1.4. Specify the response due date and the timeframe for the follow-up.

4.1.5. Ensure that the adequacy of a quality preventive action plan is determined.

4.2. The Deputy Director of Quality and Division Quality personnel will:

4.2.1. Establish the date and ensure that the effectiveness of the quality preventive action is verified.

4.2.2. Ensure that the progress of the quality preventive action is tracked.

4.2.3. Complete additional tasks regarding quality preventive action requests as defined in the appropriate Division Quality Assurance Manual (s).

4.3. Individual(s) and designees responsible for handling the quality preventive action will:

4.3.1. Identify and report quality preventable actions to management.

4.3.2. Plan and implement quality preventive action(s) by the due date.

4.3.3. Return the Quality Preventive Action Request to the Deputy Director of Quality and the initiating Laboratory Manager by the due date.

4.3.4. Provide objective evidence of completion of the preventive action to the Deputy Director of Quality and the initiating Laboratory Manager.

5. Practices

5.1. Quality preventive actions are undertaken to identify opportunities for improvement and to reduce the likelihood of a nonconformity occurring. If a condition or situation exists that may be improved, the DFS employee identifying the opportunity will notify the Laboratory Manager, the Deputy Director of Quality or Division Director. If a quality preventive action is identified through an internal audit or assessment, the Laboratory Manager and/or Deputy Director of Quality, Division Director or Directorate member will initiate the Quality *Preventive Action Request.*

5.2. Quality Preventive Action Request

5.2.1. The Laboratory Manager and/or Deputy Director of Quality will evaluate the proposed preventive action. If a Quality *Preventive Action Request* is warranted, a person will be assigned to develop the action plan, manage the preventive action and initiate the Quality *Preventive Action Request*. This form identifies the individual who is responsible for handling the quality preventive action, management approval for plan implementation, specific milestone dates to track the progress of the chosen quality preventive action, and the date of completion of the quality preventive action steps.

5.3. Verification of Effectiveness

5.3.1. The Laboratory Manager, Division Director and/or Deputy Director of Quality will ensure that the effectiveness of the quality preventive action is verified. This verification may be accomplished by reviewing the objective evidence of completion.

5.3.2. When the Quality *Preventive Action Request* has been verified, the Laboratory Manager, Division Director and/or Deputy Director of Quality shall inform the laboratory staff and/or individual analyst of the completion of the process. Memorandum should be the method used to convey this information.

5.4. Monitoring

5.4.1. After a quality preventive action is completed and closed out, the Laboratory Manager, Division Director or Deputy Director of Quality will ensure that periodic monitoring is performed within the established timeframe as necessary to assess the continued effectiveness of the quality preventive action. The monitoring may be accomplished by subsequent audits.

6. Documentation

6.1. The following records shall be generated and retained for at least one accreditation cycle or five years, whichever is longer:

6.1.1. *Quality Preventive Action Request* with the associated responses

7. References

7.1. *ISO/IEC 17025 – General Requirements for the Competence of Testing and Calibration Laboratories*, International Organization for Standardization, Geneva, Switzerland (current revision).

7.2. *ASCLD/LAB-International® Supplemental Requirements for the Accreditation of Forensic Science Testing and Calibration Laboratories*, American Society of Crime Laboratory Directors/Laboratory Accreditation Board, Garner, NC (current revision).

7.3. Forensic Quality Services Supplemental Requirements for Forensic Testing, FQS ANSI-ASQ Accreditation Board, Tampa, FL (current revision)

7.4. *Quality Assurance Standards for Forensic DNA Testing Laboratories*, Federal Bureau of Investigation, (current revision).

7.5. *Forensic Science Laboratory Quality Assurance Manual* (current revision)

7.6. Unit-specific *Quality Assurance Manual* (current revision)

7.7. Division-specific Quality Assurance Manual

7.8 Forensic Quality Services Supplemental Requirements, FQS ANSI-ASQ Accreditation Board

7.9 Record Retention Policy